DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NDO Surgical, Inc.
Mr. John J. Vozella
VP RA/Clinical/QA
125 High Street, Suite 7
Mansfield, MA 02048

JUL 27 2015

Re: K073671
Trade/Device Name: Plicator GSX™ Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): December 21, 2007
Received (Date on orig SE ltr): December 27, 2007

Dear Mr. Vozella,

This letter corrects our substantially equivalent letter of March 26, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K073671

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K073671

Device Name: Plicator GSX™ Suturing System

Indications for Use: The Plicator GSX™ Suturing System is indicated for the endoscopic placement of sutures to approximate and fixate gastrointestinal soft tissue.

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073671

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K073671

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5. 510(K) SUMMARY

MAR 2 6 2008

1. SUBMITTER:

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Mansfield, MA 02048
Telephone: 508-337-8881
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Contact: John J. Vozella, V.P. Regulatory/Clinical/QA
Date Prepared: December 21, 2007

2. DEVICE:

Trade Name: Plicator GSX™ Suturing System
Common Name: Endoscope accessory
Classification Name: Endoscope and accessories
Class: II

3. PREDICATE DEVICE:

NDO Surgical Plicator™ Endoscopic Plication System (K071533; K072125)
Bard® EndoCinch™ Suturing System (K994290; K003956)
EndoGastric StomaphyX Device and Accessories (K062875)
InScope Tissue Apposition System (K070151)

4. DEVICE DESCRIPTION:

The Plicator GSX Suturing System (GSX) deploys a pledgeted, suture to approximate and secure tissue within the gastrointestinal tract. The GSX consists of four procedural components: the Plicator® instrument, the Plicator® tissue retractor, the Plicator® tissue grasper and the Plicator GSX™ suture cartridge. The Plicator instrument's shaft, which comes into contact with the patient, is made of polyurethane. The retractor is made of surgical grade stainless steel, with a polycarbonate sheath. The grasper is made of surgical grade stainless steel, with a nitinol connecting rod and arms. The pledgeted suture is comprised of two titanium retention bridges, 2.0 polypropylene suture and two ePTFE pledgets. The suture is housed in a disposable cartridge. Procedurally, the suture cartridge and either the retractor or the grasper are loaded onto the instrument and the instrument is then passed transorally into the gastrointestinal tract to deploy the suture and secure tissue. Once the Plicator instrument has been introduced transorally, the retractor or grasper is engaged into soft tissue in the gastrointestinal tract and the tissue is retracted into the arms of the instrument. The arms of the instrument are closed and the suture is deployed, creating a transmural fixation of soft tissue.

5. INTENDED USE:

The Plicator GSX™ Suturing System is indicated for the endoscopic placement of sutures to approximate and fixate gastrointestinal soft tissue.

6. COMPARISON OF CHARACTERISTICS:

The proposed Plicator GSX™ Suturing System (GSX), is identical in design, materials and fundamental operating principles to the predicate Plicator Endoscopic Plication System (EPS) device (K023234, K032820, K071533), except that:

- the Plicator GSX pre-tied, pledgeted suture will be offered in two different lengths (the EPS only offers one suture length),
- a tissue grasper is being offered as a procedural accessory component to the GSX system (the predicate EPS does not include this accessory component) and
- a cartridge release accessory (CRA) is being offered as a non-procedural accessory component to the GSX system (the predicate EPS does not include this accessory component).

The GSX System is also similar to the other listed predicate devices in that they are all designed to reach the desired suture location under endoscopic visualization, grasp tissue in some fashion and place sutures, clips or fasteners in a targeted soft tissue location. All devices share common features such as: single-use sterile components and delivery of the soft tissue fixation component via manual actuation of a mechanism on the deployment system. Finally, the Plicator GSX™ Suturing System and the predicate devices have the same or similar intended use, which is to endoscopically place sutures, clips or fasteners to approximate soft tissue.

7. PERFORMANCE DATA:

Bench and animal testing of the Plicator GSX™ Suturing System demonstrated that the system is able to safely and reliably deploy multiple pledgeted sutures. Bench testing confirmed that the GSX pledgeted suture meets USP requirements and testing in the porcine animal model demonstrated successful closure of gastric perforations, with normal results for the healing process.

Biocompatibility testing per ISO 10993-1: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing confirmed acceptable biocompatibility profiles of patient contact materials used in the Plicator GSX™ Suturing System.

Published clinical treatment outcomes demonstrate that placement of multiple, GSX pledgeted sutures safely and effectively closes gastric wall defects.

8. CONCLUSION:

Based on the intended use, descriptive information and performance evaluation provided in this submission, the Plicator GSX™ Suturing System has been shown to be equivalent in technology, method of operation and intended use to the currently marketed predicate devices.